

Amendment:

Please enter the following supplemental preliminary amendments before examination on the merits.

IN THE CLAIMS:

Please amend the claims as follows:

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42. (Twice Amended) A process for preparing controlled release compositions characterized by burst-free, sustained, programmable release of biologically active agents, comprising: dissolving biodegradable poly(lactide/glycolide), in uncapped form and biodegradable poly(lactide/glycolide) in end-capped form in methylene chloride, and dissolving a biologically active agent or active core in water; adding the aqueous layer to the polymer solution and emulsifying to provide an inner water-in-oil (w/o) emulsion; stabilizing the w/o emulsion in a solvent-saturated aqueous phase containing an oil-in-water (o/w) emulsifier; adding said w/o emulsion to an external aqueous layer containing oil-in-water emulsifier to form a ternary emulsion; and stirring the resulting water-in-oil-in-water (w/o/w) emulsion for sufficient time to remove said solvent, and rinsing hardened microcapsules with water and lyophilizing said hardened microcapsules.

Please add the following new claims

158. (New) The process of claim 42, wherein the biologically active agent is a polypeptide.

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159. (New) The process of claim 158, wherein said polypeptide is any of the vaccine agents against enterotoxigenic *E. coli* selected from the group consisting of CFA/I, CFA/II, CS1, CS3, CS6, and CS17, ETEC-related enterotoxins, and combinations thereof.

160. (New) The process of claim 159, wherein said polypeptide is CFA/I.

161. (New) The process of claim 160, wherein said CFA/I polypeptide is synthetic and is selected from the group of synthetic peptides containing the CFA/I pilus protein T-cell epitopes (Starting Sequence # given)

4(Asn-Ile-Thr-Val-Thr-Ala-Ser-Val-Asp-Pro),
8(Thr-Ala-Ser-Val-Asp-Pro-Val-Ile-Asp-Leu),
12(Asp-Pro-Val-Ile-Asp-Leu-Leu-Gln-Ala-Asp),
15(Ile-Asp-Leu-Leu-Gln-Ala-Asp-Gly-Asn-Ala),
20(Ala-Asp-Gly-Asn-Ala-Leu-Pro-Ser-Ala-Val),
26(Pro-Ser-Ala-Val-Lys-Leu-Ala-Tyr-Ser-Pro),
72(Leu-Asn-Ser-Thr-Val-Gln-Met-Pro-Ile-Ser),
78(Met-Pro-Ile-Ser-Val-Ser-Trp-Gly-Gly-Gln),
87(Gln-Val-Leu-Ser-Thr-Thr-Ala-Lys-Glu-Phe),
126(Ala-Gly-Thr-Ala-Pro-Thr-Ala-Gly-Asn-Tyr), and
133(Gly-Asn-Tyr-Ser-Gly-Val-Val-Ser-Leu-Val), and mixtures thereof;

synthetic peptides containing CFA/I pilus protein B-cell (antibody) epitopes (starting sequence given)


3(Lys-Ana-Ile-Thr-Val-Thr-Ala-Ser-Val),
11(Val-Asp-Pro-Val-Ile-Asp-Leu-Leu-Gln-Ala-Asp),
22(Gly-Asn-Ala-Leu-Pro-Ser-Ala-Val),
32(Ala-Tyr-Ser-Pro-Ala-Ser-Lys-Thr-Phe-Lys-Thr-Phe-Glu-Ser-Tyr-Arg-Val),
32(Ala-Tyr-Ser-Pro-Ala-Ser-Lys-Thr-Phe),
38(Lys-Thr-Phe-Glu-Ser-Tyr-Arg-Val),
66(Pro-Gln-Leu-Thr-Asp-Val-Leu-Asn-Ser),
93(Ala-Lys-Glu-Phe-Glu-Ala-Ala-Ala),
124(Lys-Thr-Ala-Gly-Thr-Ala-Pro-Thr),
127(Gly-Thr-Ala-Pro-Thr-Ala-Gly-Asn-Tyr-Ser),
124(Lys-Thr-Ala-Gly-Thr-Ala-Pro-Thr-Ala-Gly-Asn-Thr-Ser), and mixtures

thereof; and

synthetic peptides containing CFA/I pilus protein T-cell and B-cell (antibody) epitopes (starting sequence # given)

- 3(Lys-Asn-Ile-Thr-Val-Thr-Ala-Ser-Val-Asp-Pro),
- 8(Thr-Ala-Ser-Val-Asp-Pro-Val-Ile-Asp-Leu-Leu-Gln-Ala-Asp),
- 11(Val-Asp-Pro-Val-Ile-Asp-Leu-Leu-Gln-Ala-Asp),
- 20(Ala-Asp-Gly-Asn-Ala-Leu-Pro-Ser-Ala-Val),
- 124(Lys-Thr-Ala-Gly-Thr-Ala-Pro-Thr-Ala-Gly-Asn-Tyr-Ser), and
- 126(Ala-Gly-Thr-Ala-Pro-Thr-Ala-Gly-Asn-Tyr-Ser), and mixtures thereof.

162. (New) The process of claim 42, wherein release profiles of variable rates and duration are achieved by blending said uncapped and said end-capped forms of poly(lactide/glycolide) polymer in different ratios within the same microcapsule.

 163. (New) The process of claim 42, wherein when the ratio of uncapped polymer to end-capped polymer is increased, the release rate of the active ingredient increases.

164. (New) The process of claim 42, wherein the uncapped polymer and end-capped polymer is present in ratios ranging from 100/0 to 1/99, respectively.

165. (New) The process of claim 42, wherein the uncapped polymer and end-capped polymer is present in ratios ranging from 90/10 to 40/60.

166. (New) The process of claim 42, wherein the relative ratio between the lactide and glycolide (L/G) component is within the range of 40/60 to 0/100.

167. (New) The process of claim 42, wherein the relative ratio between the lactide and glycolide (L/G) component is within the range of 90/10 to 40/60.

168. (New) The process of claim 42, wherein the relative ratio between the lactide and glycolide (L/G) component is within the range of 48/52 to 52/48.

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